

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, January 7, 2026
Time: 9:00 am Pacific Time
Location: Zoom Teleconference
Institution: Mission Dermatology Center, Rancho Santa Margarita, CA
Principal Investigator: Shireen Guide, MD, FAAD
Protocol: Castle Creek Biosciences, LLC, CCB-EB-304
NCT Number: NCT06892639
Meeting Type: Continuing Review of Protocol and Site
Title: Evaluation of Dabocemagene Autoficel (D-Fi; FCX-007; Genetically-Modified Autologous Human Dermal Fibroblasts) for the Treatment of Wounds Due to Dystrophic Epidermolysis Bullosa

1. Call to order:

The Meeting was called to order at 9:04 am Pacific Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present was one Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

The Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for FCX-007 since it consists of autologous dermal fibroblast cells modified by a recombinant, replication-defective lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of FCX-007 locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

| | |
|---|------------------------|
| X | APPROVED |
| | CONDITIONALLY APPROVED |
| | TABLED |
| | DISAPPROVED |

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Committee recommended that, in accordance with the recent change to the Study Procedures Manual, Version 5, a needle-free vial adapter be used to withdraw the study agent from the vial into a syringe and that Biosafety SOP Section 3.3 be revised accordingly.
2. The Committee recommended that Biosafety SOP Section 3.5 be revised to include that prior to injection and at the discretion of the clinician, the dosing needle may be bent upwards to an approximate 15-degree angle to facilitate injections into the superficial plane.
3. An Institutional Representative confirmed that the water heater in the biohazardous waste storage closet is positioned within a shallow metal collection designed to contain any leaks, and that a drainpipe is attached to the pan to divert any accumulated water away from the area. The Committee determined this to be acceptable.
4. The Institutional Representative confirmed that prefilled disposable eyewash bottles are brought into the dosing rooms when a subject is being dosed. The Committee recommended that the Site Map be revised accordingly.
5. The Institutional Representative confirmed that the plumbed eyewash station is flushed on a weekly basis, and a log of this action is maintained on-site.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

| | |
|---|------------------------|
| X | APPROVED |
| | CONDITIONALLY APPROVED |
| | TABLED |
| | DISAPPROVED |

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:18 am Pacific Time.